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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,985	09/25/2003	Jaime L. Rugnetta	279.607US1	4509

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EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,985	RUGNETTA ET AL.	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 8 (and 9-14 depending therefrom) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation " the at least one first recessed portion longitudinally disposed between the tine coupling portion and the at least one second recessed portion" at lines 16-17. There is insufficient antecedent basis for the limitations "the at least one first *recessed* portion" (emphasis added) and "the at least one second *recessed* portion" (emphasis added) in the claim. It is unclear whether or not claim 8 requires the first and second portions to be recessed. Appropriate correction is required.

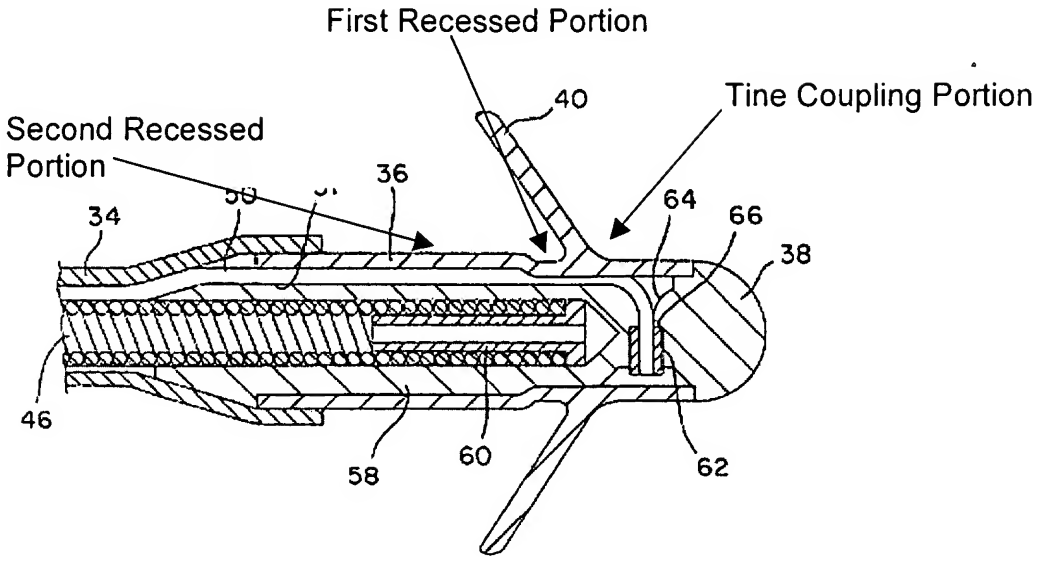
Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-4, 6-10, 12, 14-16, and 19-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,289,251 ("Huepenbecker et al."), as described in the previous Office Action dated 1/27/06. For reference purposes, the rejection of 1/27/06 has been provided below.

Huepenbecker et al. discloses a lead having at least one tine (40) coupled at the distal end thereof. The tines have a first position extended away from the lead body (as shown in Figure 4 reproduced below). In addition, although not explicitly stated, the tines necessarily have a second collapsed position because the tines of formed of a flexible material such that the tines folds/collapse against the lead body during insertion into the patient. The lead includes two recessed portions, as indicated on Fig. 4 reproduced below. The first recessed portion is longitudinally disposed between the tine coupling portion and the second recessed portion, as shown below. In addition, when the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine.



With respect to claims 3, 9, and 19-20, the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion.

With respect to claim 4, it appears from Figure 4 that the cross-sectional area at the lead distal end (between electrode 38 and the tine- coupling portion) is approximately the same as the cross-sectional area of the tine coupling portion. Accordingly, the cross-sectional area of the tine coupling area is necessarily "less than 10% smaller" than the cross-sectional area of the lead distal end.

With respect to claim 6, the length of the first recessed portion is less than the tine length.

With respect to claim 7, Examiner considers spacer 34 shown on Figure 4 to be an "intermediate portion of the lead body." As shown in Fig. 4, the diameters of the

spacer 34, the first recessed portion, and the second recessed portion are each different from one another.

With respect to claim 8, the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion. As such, Examiner considers the first cross-sectional shape to be different from the second cross-sectional shape. In the alternative, Examiner notes that the 103 rejection below for claims 17-18 relate to modifying the first and/or second recessed areas to be non-circular (thus resulting in the first cross-sectional shape being different from the second cross-sectional shape).

With respect to claim 15, the lead disclosed in Huepenbecker et al. is necessarily formed by the method of claim 15.

5. Claims 1, 3-4, 6-10, 12, 14-16, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,807,399 ("Laske et al."), as described in the previous Office Action dated 1/27/06. For reference purposes, the rejection of 1/27/06 has been provided below.

Laske et al. discloses a lead having at least one tine (124) coupled at the distal end thereof. The tines have a first position extended away from the lead body (as shown in Figure 5 reproduced below). In addition, although not explicitly stated, the tines necessarily have a second collapsed position because the tines of formed of a soft, pliant material such that the tines folds/collapse against the lead body during insertion into the patient (see col. 5, lines 23-37). The lead includes two recessed

portions, as indicated on Fig. 5 reproduced below. The first recessed portion is longitudinally disposed between the tine coupling portion and the second recessed portion, as shown below. In addition, when the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine.

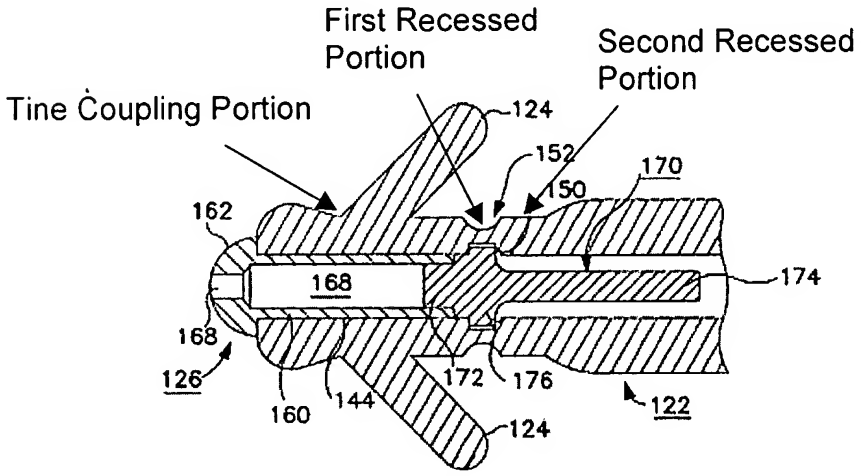


FIG. 5

With respect to claims 3, 9, and 19-20, the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion.

With respect to claim 4, it appears from Figure 5 that the cross-sectional area at the lead distal end is slightly larger than the cross-sectional area of the tine coupling portion. Examiner considers the cross-sectional area of the tine coupling area to be approximately "less than 10% smaller" than the cross-sectional area of the lead distal end.

With respect to claim 6, the length of the first recessed portion is less than the tine length.

With respect to claim 7, Examiner considers tubular sheath 122 shown on Figure 5 to be an "intermediate portion of the lead body." As shown in Fig. 5, the diameters of the sheath 122, the first recessed portion, and the second recessed portion are each different from one another.

With respect to claim 8, the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion. As such, Examiner considers the first cross-sectional shape to be different from the second cross-sectional shape. In the alternative, Examiner notes that the 103 rejection below for claims 17-18 relate to modifying the first and/or second recessed areas to be non-circular (thus resulting in the first cross-sectional shape being different from the second cross-sectional shape).

With respect to claim 15, the lead disclosed in Laske et al. is necessarily formed by the method of claim 15.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 2, 5, 11, 13, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,289,251 ("Huepenbecker et al.") in view of U.S. Patent No. 5,531,781 ("Alferness et al.").

As discussed above, Huepenbecker et al. discloses a lead having two recessed portions at the tine interface section of the lead body. Huepenbecker et al. fails to disclose that the recessed portions extend only a portion around the perimeter of the lead body. Although not explicitly stated, it is well known in the art to utilize a space such as the recessed portions for receiving flexible tines during implantation, thereby minimizing the cross-section of the lead at the tine interface area during implantation. For example, Alferness et al. teaches a variety of embodiments in which a plurality of tines are received in a space or spaces formed within the lead body (see Figs. 6, 8, and 10 and corresponding text at col. 6, line 8 - col. 7, line 20). Such recesses are only required at the area in which the tines contact the lead body (see Figs. 8 and 10 and associated text). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the first and/or second recessed portions of Huepenbecker et al. such that recesses are created only at the area in which the tines contact the lead body as taught by Alferness et al. in order to ensure that lead body is sufficiently strong during implantation.

With respect to claim 5, Huepenbecker et al. fails to disclose that the lead body has a first transverse dimension and a second transverse dimension each at a longitudinal location along the first recessed portion, and the first transverse dimension is greater than the second transverse dimension. Modifying the first recessed portion of

Huepenbecker et al. such that recesses are created only at the area in which the tines contact the lead body as taught by Alferness et al., as described above, necessarily results in a lead body having a first transverse dimension which is greater than a second transverse dimension (see Figs. 8 and 10 of Alferness et al.).

With respect to claims 17-18, Huepenbecker et al. fails to disclose that forming the recessed portions includes forming non-circular cross-sections at the tine interface portion. Modifying the first and/or second recessed portions of Huepenbecker et al. such that recesses are created only at the area in which the tines contact the lead body as taught by Alferness et al., as described above, necessarily results in creating non-circular cross-sections.

8. Claims 2, 5, 11, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,807,399 ("Laske et al.").

As discussed above, Laske et al. discloses a lead having two recessed portions at the tine interface section of the lead body. Laske et al. fails to disclose that the first recessed portion extends only a portion around the perimeter of the lead body. The first recessed portion (external groove 152) defines a zone in which the sheath 122 may be readily separated (see col. 7, lines 15-50). Laske et al. utilizes the first recessed portion to create a weakened area in the sheath 122. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the external groove 152 of Laske et al. such that it only extends around a portion of the perimeter of the lead body (so long as the sheath 122 may be readily separated when force is

applied thereto) in order to ensure that sheath 122 is sufficiently strong during implantation.

With respect to claim 5, Laske et al. fails to disclose that the lead body has a first transverse dimension and a second transverse dimension each at a longitudinal location along the first recessed portion, and the first transverse dimension is greater than the second transverse dimension. Modifying the external groove 152 of Laske et al. such that it only extends around a portion of the perimeter of the lead body, as described above, necessarily results in a lead body having a first transverse dimension which is greater than a second transverse dimension.

With respect to claim 17, Laske et al. fails to disclose that forming the first recessed portion includes forming a non-circular cross-section at the tine interface portion. Modifying the external groove 152 of Laske et al. such that it only extends around a portion of the perimeter of the lead body, as described above, necessarily results in creating a non-circular cross section.

9. Claims 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,807,399 ("Laske et al.") in view of U.S. Patent No. 5,531,781 ("Alferness et al.").

As discussed above, Laske et al. discloses a lead having two recessed portions at the tine interface section of the lead body. Laske et al. fails to disclose that the second recessed portion extends only a portion around the perimeter of the lead body. Although not explicitly stated, it is well known in the art to utilize a space such as the

second recessed portion for receiving flexible tines during implantation, thereby minimizing the cross-section of the lead at the tine interface area during implantation. For example, Alferness et al. teaches a variety of embodiments in which a plurality of tines are received in a space or spaces formed within the lead body (see Figs. 6, 8, and 10 and associated text). Such recesses are only required at the area in which the tines contact the lead body (see Figs. 8 and 10 and associated text). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the second recessed portion of Laske et al. such that the recess is created only at the area in which the tines contact the lead body as taught by Alferness et al. in order to ensure that sheath 122 is sufficiently strong during implantation.

With respect to claim 18, Laske et al. fails to disclose that forming the second recessed portion includes forming a non-circular cross-section at the tine interface portion. Modifying the second recessed portion of Laske et al. such that the recess is created only at the area in which the tines contact the lead body as taught by Alferness et al., as described above, necessarily results in creating a non-circular cross-section.

Response to Arguments

10. Applicant's arguments filed 5/26/06 have been fully considered but they are not persuasive.

11. More specifically, Applicant argues that Huenpenbecker does not teach a recessed portion recessed away from the bottom of the tine when the tine is disposed in a second collapsed position. In support of such an argument, Applicant notes that

Huenpenbecker does not include any figures illustrating tines in a collapsed position. As explained in the rejection, although not explicitly stated in Huenpenbecker, passive tines such as the ones illustrated in Huenpenbecker are necessarily are formed of a flexible material such that the tines fold/collapse against the lead body during insertion into the patient (see, for example, U.S. Patent No. 5,531,781 to Alferness which teaches that tines are formed as flexible and pliant such that they collapse and do not interfere with or impede steering during implantation of the lead; see col. 6, lines 35-40. See also U.S. Patent No. 5,571,157 which describes that tines flatten against the lead body thus reducing its diameters such that the tined lead is suitable for introduction through small blood veins; see col. 1, lines 45-55. In addition, see U.S. Patent No. 4,409,994 which teaches foldable tines which collapse against the lead body recessed portion during implantation of the lead). In order to implant the lead distal end at the heart such that it can provide the desired pacing or defibrillation therapy, the tines necessarily must fold down/collapse against the lead body such that the lead can be tracked through a patient's vasculature system to the implantation site of the right ventricular apex (see col. 2, line 59).

In addition, when the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine because the bottom surface of tines would contact the outer surface of sleeve 36 (which forms the second recessed portion), thus leaving the first portion (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine.

With respect to the rejection of claim 8 based on Huenpenbecker, the cross-sectional area of the first recessed portion is illustrated in Figure 4 as smaller than the cross-sectional area of the second recessed portion. As such, Examiner considers the first cross-sectional shape to be different from the second cross-sectional shape. In the alternative, Examiner notes that the 103 rejection above for claims 17-18 relate to modifying the first and/or second recessed areas to be non-circular (thus resulting in the first cross-sectional shape being different from the second cross-sectional shape).

One of Applicant's arguments appears to be that since Huenpenbecker does not state that the drawings are to scale, the Figure 4 of Huenpenbecker cannot anticipate the claims of the present invention. Examiner notes that the claims as written do not require any precise proportions or sizes of the first and second recessed portions. Although patent drawings which are not disclosed as drawn to scale may not be relied on to show particular sizes if the specification is completely silent on the issue, the drawings and pictures can anticipate claims if they clearly show the structure which is claimed. See MPEP 2125. Examiner considers Fig. 4 of Huenpenbecker to clearly show claimed structures of the present invention: the lead body, at least one tine, and the first and second recessed portions formed on the lead body.

12. Applicant also argues that Laske does not teach a recessed portion recessed away from the bottom of the tine when the tine is disposed in a second collapsed position. In support of such an argument, Applicant notes that Laske does not include any figures illustrating tines in a collapsed position. As explained in the rejection,

although not explicitly stated in Laske, tines such as the ones illustrated in Laske are necessarily are formed of a flexible material such that the tines fold/collapse against the lead body during insertion into the patient (see, for example, U.S. Patent No. 5,531,781 to Alferness which teaches that tines are formed as flexible and pliant such that they collapse and do not interfere with or impede steering during implantation of the lead; see col. 6, lines 35-40. See also U.S. Patent No. 5,571,157 which describes that tines flatten against the lead body thus reducing its diameters such that the tined lead is suitable for introduction through small blood veins; see col. 1, lines 45-55. In addition, see U.S. Patent No. 4,409,994 which teaches foldable tines which collapse against the lead body recessed portion during implantation of the lead). More specifically, Laske incorporates by reference U.S. Patent No. 3,902,501 to Citron et al., which teaches that the tines fold/collapse against the lead body during insertion into the patient (see Figures 6 and 11 of Citron et al. and associated text). In order to implant the lead distal end at the heart such that it can provide the desired pacing therapy, the tines necessarily must fold down/collapse against the lead body such that the lead can be tracked through a patient's vasculature system to the implantation site of the endocardium.

In addition, when the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine because the bottom surface of tines would contact the outer surface lead body (which forms the second recessed portion), thus leaving the first portion or groove 152 (which is

illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine.

With respect to the rejection of claim 8 based on Laske, the cross-sectional area of the first recessed portion is illustrated in Figure 5 as smaller than the cross-sectional area of the second recessed portion. As such, Examiner considers the first cross-sectional shape to be different from the second cross-sectional shape. In the alternative, Examiner notes that the 103 rejection above for claims 17-18 relate to modifying the first and/or second recessed areas to be non-circular (thus resulting in the first cross-sectional shape being different from the second cross-sectional shape).

One of Applicant's arguments appears to be that since Laske does not state that the drawings are to scale, the Figure 5 of Laske cannot anticipate the claims of the present invention. Examiner notes that the claims as written do not require any precise proportions or sizes of the first and second recessed portions. Although patent drawings which are not disclosed as drawn to scale may not be relied on to show particular sizes if the specification is completely silent on the issue, the drawings and pictures can anticipate claims if they clearly show the structure which is claimed. See MPEP 2125. Examiner considers Fig. 5 of Laske to clearly show claimed structures of the present invention: the lead body, at least one tine, and the first and second recessed portions formed on the lead body.

13. With respect to claims 2, 5, 11, 13, and 17-18, Applicant next argues that the motivation statement to combine Huenpenbecker (or Laske) and Alferness et al. is

unsupported by the references. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine the references (to ensure that the lead body is sufficiently strong during implantation) is based on common sense and in the knowledge generally available to one of ordinary skill in the art. Added material in the area of the recesses 167, as shown in Figure 10 of Alferness et al., would necessarily strengthen the lead body at the distal end thereof such that it is sufficiently strong to be tracked through a patient's vasculature system to the implantation site of the endocardium.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 4,409,994 (which correspond to GB 2099307 cited in applicant's IDS) teaches a lead having a recessed portion (31) to receive tines 33 and 35.

U.S. Patent No. 5,571,157 teaches a lead having a small diameter recess (48) for receiving tines 30 (see Figure 1 and associated text at col. 5, lines 1-10).

U.S. Patent No. 5,645,580 teaches a lead having a recess (88) for receiving tines 84 (see Figure 3 and associated text at col. 6, lines 28-55).

U.S. Patent No. 6,006,139 discloses a lead having a distal end 104 (see, for example, Figure 15), which includes tines and two recessed portions at the tine interface portion.

U.S. Patent Application Publication 2004/0034401 teaches a lead fixation arrangement in which a plurality of tines each have their own corresponding elongated recess for receiving the tine body (see paragraph 0028).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-

8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRK
6/1/06

George Manuel
Primary Examiner